K041170

NOV - 9 2004

Traditional 510(k) Summary of Safety and Effectiveness for the MODIFICATION TO SECUR-FIT™ HA AND SECUR-FIT™ PLUS HIP STEMS

Proprietary Name:	Secur-Fit™ HA and Secur-Fit™ Plus Hip Stems
Common Name:	Artificial Hip Components
Classification Name and Reference	Hip joint, metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prostheses, 21 CFR §888.3353
Regulatory Class:	Class II
Device Product Code:	87 MEH, 87 LZO
For Information contact:	Karen Ariemma Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, New Jersey 07430 Phone: (201) 831-5718 Fax: (201) 831-6038 E-Mail: karen.ariemma@stryker.com
Date Summary Prepared:	November 4, 2004

Device Description

The currently marketed Osteonics® Secur-Fit™ HA and Secur-Fit™ Plus Hip Stems were revised to incorporate a streamlined neck geometry and modify the C-Taper trunnion length.

Intended Use:

The Osteonics® Secur-Fit™ HA and Secur-Fit™ Plus Hip Stems are single-use devices and are intended for cementless fixation within the prepared femoral canals of patients requiring hip arthroplasty.

Indications for Use

The indications for use of the Osteonics® Secur-Fit™ HA and Secur-Fit™ Plus Hip Stems as a Total Hip Replacement include:

- Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and
- Treatment of non-union, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Substantial Equivalence:

The features of the modified stems are substantially equivalent to the corresponding features of the predicate Osteonics® Secur-Fit™ HA and Secur-Fit™ Plus Hip Stems determined substantially equivalent via 510(k)s K941366, K951517, 982032, K990203, and K020615. The modified stems are similar to the predicate stems in every aspect with the exception of the streamlined neck geometry and the modified C-Taper trunnion length. The testing used to evaluate the subject stems demonstrates substantial equivalence of the modified device to the predicate device in regards to neck strength. In addition, the intended use, material, manufacturing methods, packaging, package insert, and sterilization of the modified and unmodified stems are identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 9 2004

Ms. Karen Ariemma
Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K041170
Trade/Device Name: Modification to Secur-Fit™ HA and Secur-Fit™ Plus Hip Stems
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint, metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Codes: LZO, MEH
Dated: October 15, 2004
Received: October 21, 2004

Dear Ms. Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

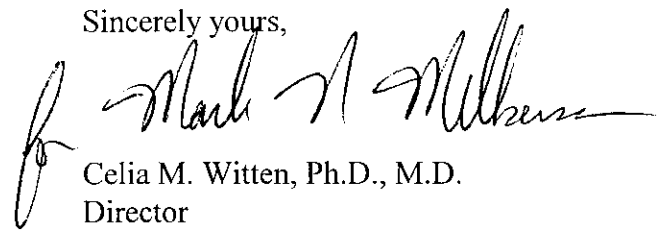
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041170

Device Name: Modification to SECUR-FIT™ HA and SECUR-FIT™ PLUS Hip Stems

Indications For Use:

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- Treatment of non-union, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Millburn

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K041170